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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,319	07/15/2005	Philippe A. Tessier	6013-149us	3470

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EXAMINER	
WEN, SHARON X	
ART UNIT	**PAPER NUMBER**
1644	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,319	TESSIER ET AL.	
	Examiner	Art Unit	
	Sharon Wen	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :04/28/2006, 07/19/2006, 12/15/2006 and 03/30/2007 .

DETAILED ACTION

1. The Art Unit location of the examiner of this application in the PTO has changed. To aid in the correlating any papers for this application, all further correspondence regarding this application should be directed to Sharon Wen, Group Art Unit **1644**, Technology Center 1600.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/30/2007 has been entered.

3. Applicant's amendments, filed 07/11/2007, have been entered.

Election/Restrictions

4. In accordance with telephone conversation with Applicant's representative, Louise Bernier, on 07/06/2007, Applicant provisionally elected the subject matter of claim 1 as amended, namely "*a method for inhibiting recruitment...said method comprising administering to said individual an antibody against a S100A8 protein and an antibody against S100A9 protein.*"

5. Applicant's election of species "an antibody against S100A8 and an antibody against S1009", "gout" and "intravenous administration" in Response to Election/Restriction filed on 07/11/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Upon further consideration, the examination has been extended to include species "subcutaneous" recited in claim 5.

6. Claims 2, 4 and 8-13 have been cancelled.

Claims 1, 3 and 5-7 are pending and currently under examination as they read on a method for inhibiting the recruitment and activation of neutrophils associated with gout comprising administering an antibody against a S100A8 protein and an antibody against S100A9 protein.

Priority

7. The effective priority date for claims 1, 3 and 5-7 is deem the filing date of provisional application, USSN 60/393,520, i.e., 07/05/2002.

Information Disclosure Statement

8. Applicant's IDSs, filed on 04/28/2006, 07/19/2006, 12/15/2006 and 03/30/2007 are acknowledged, and have been considered.

Specification

9. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

10. Applicant is invited to review and correct all spelling errors, TRADEMARKS, embedded hyperlinks and/or other form of browser-executable code, and like errors (e.g., see page 4 first paragraph and page 8, line 26).

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademark is permissible in patent application, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1 and 5-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Hanash (US 2002/0192228 A1, see entire document) as evidenced by Seto et al. (US Patent 6,706,683 B1, see entire document).

Hanash teaches a method for inhibiting the recruitment and activation of neutrophils comprising intravenous and subcutaneous administration of antibodies against S100A8 and S100A9 in a human (e.g., see paragraphs [0110]-[0112], [0115]-[0116], and [0125]).

Although Hanash is silent on using an antibody against S100A8 and an antibody against S100A9, per se, given the reference teaches a polyclonal antibody against an antigen formed by heterodimerization of S100A8 and S100A9 that cross reacts with both proteins (see paragraph [0112] and [0125]), one of ordinary skill would have immediately recognized that the prior art polyclonal antibodies would comprise at least one antibody against S100A8 and at least one antibody against S100A9 because it is an inherent property of polyclonal antibodies to contain a mixture of antibodies with different epitopic specificities to the same antigen.

Hanash does not use the names of the proteins recited in the instant claims, S100A8 and S100A9, per se. However, S100A8 and S100A9 are known in the art as MRP8 and MRP14, respectively, as evidenced by Seto et al. (see column 2, lines 7-12).

It does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories* 58 USPQ2d 1508 (CAFC 2001). Though the reference is silent on "inhibiting recruitment and activation of neutrophils", one of ordinary skill would readily recognize that the same method steps comprising administering an antibody against S100A8 and an antibody against S100A9, such as the one taught by the reference, would also be capable of "inhibiting recruitment and activation of neutrophils" in the present claims.

There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claims 1, 3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seto et al. (WO00/18970 published in Japanese) as evidenced by its English translation in US Patent 6,706,683 B1, in view of Dinerstein et al (US Patent 5,248,825) and Hanash (US 2002/0192228 A1).

Seto et al. teach using antibodies against S100A8 and S100A9 to inhibit activation of neutrophil (US Patent 6,706,683 B1 see entire document, in particular, Background Art, column 1, lines 45-50; column 2, lines 7-9; and column 8 lines 1-52). The reference teach that secretion of granules by neutrophils can be inhibited by administering polyclonal antibodies to calgranulin, which comprise calgranulin A (aka S100A8) and calgranulin B (aka S100A9) into cell lines (see column 8, lines 1-52).

Although Seto does not teach using the antibody for "inhibiting recruitment and activation of neutrophils", one of ordinary skill would recognize that the same antibodies would also have the same properties of "inhibiting recruitment and activation of neutrophils".

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada* 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

Seto et al. differs from the instant claims by not teaching treating gout by inhibiting neutrophils.

However neutrophil involvement in gout is well known in the art as evidenced by Dinerstein et al. (see entire document). In particular, Dinerstein et al. teach that neutrophils play an integral part in the pathogenesis of gout (see column 2, lines 17-19) and that neutrophil recruitment in the afflicted tissue area in gout is well documented (see column 14, line 15-30).

Dinerstein et al. and Seto et al. do not teach administering antibodies to patients.

However, it is well known in the art to administer antibodies against S100A8 and S100A9 to human, as exemplified by the teaching of Hanash, discussed supra.

Taken together, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to administer antibodies against S100A8 and S100A9 to human, as taught by Hanash, for inhibiting the recruitment and activation of neutrophils, as taught by Seto et al., for treating diseases such as gout, as taught by Dinertein et al.

Furthermore, one of ordinary skill would have been motivated to administer antibodies against S100A8 and S100A9 to human for treating gout because of the teaching by Seto et al. stating that "substances with inhibit secretion of neutrophil granules are thought to be useful as a therapeutic drug for treating disease associated with secretion of neutrophil granules" (column 1, lines 46-50).

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

15. No claim is allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon Wen whose telephone number is (571) 270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571)272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Wen, Ph.D.
Patent Examiner
August 17, 2007

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
8/20/07